# **REMARKS/ARGUMENTS**

Upon entry of the present amendment, claims 1-6, 8-10, and 12-16 will be pending in this application and presented for examination. Claim 7 and 17 have been canceled without prejudice or disclaimer. Claims 1 and 16 have been amended. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

# I. FORMALITIES

Claim 1 has been amended by incorporating the features of claim 7. Claim 7 has been canceled without prejudice. The Examiner has acknowledged that claim 7 is not anticipated by the cited art.

Claim 16 has been amended by deleting the phrase "mixtures thereof" and inserting in lieu therefor --said at least one detergent--. Support for "at least one detergent" is found in claim 1 as filed. In view of the foregoing support, Applicants respectfully request that the Examiner enter the amendments.

# II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 16 and 17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly introducing new matter into the claims. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Claim 16 has been amended by inserting --said at least one detergent--; and deleting "mixtures thereof". The phrase "said at least one detergent" finds support in the application as originally filed (claim 1 of the original PCT application). A skilled person would understand that the phrase "said at least one" means that the detergent could be one detergent or more than one detergent. If the composition contains more than one detergent (*e.g.*, two detergents), it is by definition "a mixture of detergents." Therefore, even though Applicants have deleted "mixtures thereof," the term was redundant in view of the "at least one" language.

Therefore, no subject matter has been surrendered in view of this amendment. As such, Applicants respectfully request that the Examiner withdraw the rejection.

Claim 17 has been canceled thereby rendering this rejection moot. The cancellation of claim 17 does not surrender any subject matter, as claim 3 sets forth the embodiment wherein the bulking agent is present in an amount greater than 50% by weight of the composition. In view of the foregoing cancellation of the claim, Applicants respectfully request that the Examiner withdraw the rejection.

# III. REJECTION UNDER 35 U.S.C. § 102(b)

Claims 1, 4-6, 8, 10, 14 and 16 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,866,152 ("the '152"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants have added the phrase "wherein said substantially non-aqueous shampoo, contains less than 20% water." Support is found, for example, at page 3, line 18; and claim 7. In the Office Action, the Examiner has acknowledged that claim 7 is not anticipated by the '152 patent. As this feature is now incorporated into the base claim, the Examiner has in effect, acknowledged that the claims are not anticipated by the '152 patent. Therefore, Applicants respectfully request that the Examiner withdraw the anticipation rejection.

# IV. REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1-17 were rejected over the 35 U.S.C. § 103(a) as allegedly being obvious over the combination of U.S. Patent No. 5,866,152 ("the '152"), WO 87/04617 (the '617) and U.S. Patent No. 6,207,694 (the '694). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants assert that the cited references, either alone or in combination, do not teach or suggest all the limitations of the claims. The present invention teaches substantially non-aqueous liquid shampoo compositions. Applicants have amended claim 1 to set forth that the substantially non-aqueous shampoo contains less than 20% water. None of the references,

alone or in combination, teach or suggest such compositions. In fact, the Examiner has acknowledged that the '152 patent does not teach this feature.

The Examiner states that the '512 patent *suggests* at column 2, a water content of 20% or less. The Examiner alleges that this is obtained by adding the highest value for active ingredient, anionic surfactant and polyhydric alcohol. The passage of the '152 patent is reproduced below:

The shampoo composition of the present invention is usually composed of 0.001% to 5% by weight of pyriproxyfen, 10% to 70% by weight of an anionic surfactant, 0.5% to 20% by weight of a polyhydric alcohol, and water as the balance. [Emphasis added].

From the above passage, it is clear that water was intended as the fourth constituent part of the formulation. That is, the formulation was never intended to be a 3 component system as the Examiner has contemplated. Making a 3 component system from the intended 4 component system is <u>clear</u> hindsight reconstruction of the present invention. The Examiner has used the present invention as a blueprint to reconstruct the invention from the cited art.

Moreover, such a hypothetical formulation would probably be so irritating to the skin, due to the high concentrations of active that such formulation would destroy the intended purpose of the '152 invention. For example, the enclosed Material Safety Data Sheet shows that the active ingredient is a skin irritant. For example, a Material Safety Data Sheet for a pyriproxyfen containing product states:

1) **Skin Protection**: Do not get on skin or clothing. Skin contact should be minimized by wearing protective clothing including coveralls worn over short-sleeve shirts and short pants, socks, chemical resistant footwear and chemical resistant gloves.

By increasing the concentration of the active ingredient component as contemplated by the Examiner, an increase in skin irritation would result. This would destroy the intended purpose of the '152 patent.

The '617 application does not supply the deficient teaching of the primary reference. The '617 application teaches combining urea with a highly concentrated propylene glycol solution having lactic acid (*see* page 10, lines 1-2 under Conclusion). Further, the '617 does not teach or suggest the use of a detergent or even a shampoo. The '617 teaches liquid compositions containing a combination of urea, lactic acid, and high amounts of propylene glycol (*see*, page 3, lines 10-21). The concentrated formulations are used as **drops** and **penetrate** into the nail to treat onychomycosis (*see* page 7, second paragraph). Again, the '617 application teaches a formulation strong enough to **penetrate** the nail. If the concentrated material can penetrate the nail, it would also deeply penetrate the skin. Thus, this nail penetration formulation is not a shampoo as is currently taught and claimed.

In addition, the '694 patents adds nothing to the already deficient teachings. The '694 does not teach a shampoo having less than about 20% by weight water. In fact, the '694 teaches *aqueous* shampoo compositions for dandruff (Examples 1 and 4), thinning hair (Examples 2 and 5), and chemically treated hair (Example 3) containing from 47% to 86.4% of added water. The '694 patent clearly teaches **aqueous shampoo** compositions.

In the Office Action, the Examiner states that:

The WO document teaches the concentration of the bulking agent PEG as 40-80%. The WO document also teaches non-aqueous compositions. See the examples. The patent '694 teaches antidandruff compositions using the antifungal agent at the paragraph bridging cols. 2-3, and also the specific sodium laureth sulfate, specific antifungal agent of claim 13. The patent also teaches foam booster which is Betaine under example 1. With respect to claim 15 limitation optimizing the water content is within the ken of the skilled chemist.

Applicants agree with the Examiner that the WO document ("the '617 application) teaches non-aqueous compositions. However, unlike the present invention, the '617 application teaches concentrated non-aqueous formulations (not shampoos) that are used as <u>drops</u> and which <u>penetrate</u> into the nail to treat onychomycosis (*see* above). As for the teaching of the '694

patent, it is clear that the compositions as taught therein are clearly aqueous in nature. Therefore, there would be no motivation to combine the teaching of the nail penetration formulations of '617 application with the aqueous shampoo compositions of '694 patent.

As such, none of the cited references teach or suggest the substantially *non-aqueous* liquid shampoo compositions as is presently taught and claimed. According, the Examiner is respectfully requested to withdraw the obviousness rejection and send the application to issue.

# V. CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

Yoseph R. Snyde Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834

Tel: 925-472-5000 Fax: 415-576-0300 Attachments JS:jc

\_

60271189 v1

KNACK® Insect **Growth Regulator** 

This Material Safety Data Sheet (MSDS) serves different purposes than and DOES NOT REPLACE OR MODIFY THE EPA-APPROVED PRODUCT LABEL-ING (attached to and accompanying the product container). This MSDS provides important health, safety, and environmental information for employers, employees, emergency responders and others handling large quantities of the product in activities generally other than product use, while the labeling provides that information specifically for product use in the ordinary course.

Use, storage and disposal of pesticide products is requlated by the EPA under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through the product labeling. All necessary and appropriate precautionary, use, storage, and disposal information is set forth on that labeling. It is a violation of federal law to use a pesticide product in any manner not prescribed on the EPA-approved label.

#### SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: KNACK® Insect Growth Regulator

VC NUMBER(S): VC-1035
EPA REGISTRATION NUMBER: 59639-95

SYNONYM(S): S-71639 0.86 EC Pyriproxyfen 0.86 EC

V-71639 0.86 EC

MANUFACTURER

VALENT USA CORPORATION

P.O. Box 8025

1333 N. California Blvd., Suite 600 Walnut Creek, CA 94596-8025 EMERGENCY TELEPHONE NUMBERS

HEALTH EMERGENCY OR SPILL (24 hr): 1-800-

TRANSPORTATION (24 hr.): CHEMTREC 1-800-

424-9300 or (202) 483-7616 PRODUCT INFORMATION

**AGRICULTURAL PRODUCTS: 1-800-6VALENT** PROFESSIONAL PRODUCTS: 1-800-89VALENT

SECTION 2: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name (CAS #) [Chemical Name]	Weight Percent	Exposure Limit	Ref.
Pyriproxyfen* (95737-68-1) [2-[1-Methyl-2-(4- phenoxyphenoxy)- ethoxy[pyridine]	10-15	None	-
Naphthalene (91-20-3)	1 - 6	10 ppm TWA 15 ppm STEL	ACGIH, OSHA
Total Hydrocarbons (64742-94-5)	40 - 50	100 ppm	Mfg.
Other**	30 - 40	None	

- Active Ingredient
- Other ingredients, which are maintained as trade secrets, are any substances other than an active ingredient contained in this product. Some of these may be hazardous, but their identity is withheld because they are considered trade secrets. The hazards associated with the other ingredients are addressed in this document. Specific information on other ingredients for the management of exposures, spills, or safety assessments can be obtained by a treating physician or nurse by calling 1-800-892-0099 at any

# **SECTION 3: HAZARDS IDENTIFICATION**

## **EMERGENCY OVERVIEW CAUTION:**

- CAUSES SKIN AND EYE IRRITATION
- HARMFUL IF SWALLOWED, INHALED OR AB-SORBED THROUGH THE SKIN
- ASPIRATION HAZARD, DO NOT INDUCE VOMIT-
- AVOID BREATHING VAPOR OR SPRAY MIST
- DO NOT GET IN EYES, ON SKIN OR ON CLOTH-

- KEEP OUT OF REACH OF CHILDREN

POTENTIAL HEALTH EFFECTS

Acute Toxicity (Primary Routes of Exposure) Signs and Symptoms of Systemic Effects: The acute toxicity of this product is relatively low; transient, minimal signs of toxicity were observed in rats at high oral doses. This product does contain a solvent mixture. Solvents when inhaled can cause nasal and respiratory irritation and central nervous system effects including dizziness, weakness, fatigue, nausea, headache and possibly unconsciousness and even death. Ingestion of solvents can cause gastrointestinal irritation, nausea, vomiting and diarrhea. Aspiration of low viscosity solvents can cause chemical pneumonitis that can be fatal.

Eye: This product is expected to cause brief and/or minor eye irritation. The expected adverse effects resulting from an exposure may include redness and possibly some minor swelling.

Skin: This product can cause moderate skin irritation. The expected adverse health effects resulting from an exposure may include redness and swelling

This product is not expected to cause allergic skin

This product has been shown to be slightly toxic when absorbed through the skin. The expected adverse systemic health effects resulting from an exposure are described above.

Ingestion: Ingestion of this product may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Because of the low viscosity of this product, it can directly enter the lungs if it is swallowed (this is called aspiration). This can occur during the act of swallowing or when vomiting. Once in the lungs, the substance is very difficult to remove and can cause severe injury to the lungs and death.

This product has been shown to be slightly toxic when ingested. The expected adverse systemic health effects resulting from an exposure are described above. Inhalation: Exposure to very high concentrations may result in respiratory irritation. Signs and symptoms may include nasal discharge, sore throat, coughing and difficulty in breathing.

This product has been shown to be minimally toxic

when inhaled. The expected adverse systemic health effects are described above.

Chronic Toxicity (Including Cancer): Studies with Pyriproxyfen Technical indicated that repeated high exposures produced changes in the liver, kidney and red blood cells but did not produce cancer in test ani-

This product contains a solvent mixture. Reports have associated repeated and prolonged occupational overexposures to solvents with permanent brain and nervous system damage. Symptoms reported include fatigue, concentration difficulties, anxiety, depression, rapid mood swings and short term memory loss. Since many other diseases cause some or all of these conditions, a doctor should be consulted if any appear. This product contains naphthalene which has been listed by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group

Overall, this product is not expected to be a chronic hazard when used according to label directions.

Teratology (Birth Defects) Information: No developmental toxicity was produced in animals exposed to Pyriproxyfen Technical, even at doses that were toxic to the pregnant animal. This product is not expected to be a developmental hazard when used according to label directions.

Reproduction Information: Pyriproxyfen Technical did not produce reproductive toxicity in animal studies. This product is not expected to be a reproductive hazard when used according to label directions.

Potentially Aggravated Conditions: Individuals with preexisting diseases of the liver, kidney, red blood cell or central nervous system may have increased susceptibility to the toxicity of excessive exposures. For complete discussion of the toxicology data from which this evaluation was made, refer to Section 11. For Regulatory Information, refer to Section 15.

# **SECTION 4: FIRST AID MEASURES**

## **EMERGENCY NUMBER 1-800-892-0099**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-892-0099 for emergency medical treatment information.

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call a poison control center or doctor for treatment advice

## INGESTION:

- Immediately call a poison control center or doctor.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- · Do not give any liquid to the person.
- · Do not give anything by mouth to an unconscious person.

## INHALATION:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouthto-mouth, if possible,
- Call a poison control center or doctor for further treatment advice.

NOTES TO PHYSICIAN: If ingested, probable mucosal damage may contraindicate the use of gastric

This product contains a light hydrocarbon liquid; ingestion or subsequent vomiting can result in aspiration of this product, which can cause pneumonitis.

## SECTION 5: FIRE FIGHTING MEASURES

FLASH POINT: 152'F

METHOD: SetaFlash Closed Cup

**AUTOIGNITION: NDA** 

EXTINGUISHING MEDIA: CO2, dry chemical, foam,

water fog.

FLAMMABLE LIMITS (% by volume in air): Lower: NDA Upper: NDA

NFPA RATINGS: Health 2; Flammability 2; Reactivity 0; Special None

(Least-0, Slight-1, Moderate-2, High-3, Extreme-4). These values are obtained using professional judgement. Values were not available in the guidelines or published evaluations prepared by the National Fire Protection Association, NFPA.

FIRE FIGHTING INSTRUCTIONS: Liquid evaporates and forms vapor (fumes) which can catch fire and burn with explosive violence. Invisible vapor spreads easily and can be set on fire by many sources such as pilot lights, welding equipment, and electrical motors and switches. Fire hazard is greater as liquid temperature rises above 85°F.

Products of combustion from fires involving this material may be toxic. Avoid breathing smoke and mists. Avoid personnel and equipment contact with fallout and runoff. Minimize the amount of water used for fire fighting. Do not enter any enclosed area without full protective equipment, including self-contained breathing equipment. Contain and isolate runoff and debris for proper disposal. Decontaminate personal protective equipment and fire fighting equipment before reuse. Read the entire document.

HAZARDOUS COMBUSTION PRODUCTS: Normal combustion forms carbon dioxide, water vapor and may produce oxides of nitrogen. Incomplete combustion can produce carbon monoxide.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

VALENT EMERGENCY PHONE NUMBER: 1-800-892-0099

CHEMTREC EMERGENCY PHONE NUMBER: 1-800-424-9300

**OBSERVE PRECAUTIONS IN SECTION 8: PER-**SONAL PROTECTION

Stop the source of the spill if safe to do so. Contain the spill to prevent further contamination of the soil, surface water, or ground water. FOR SPILLS ON LAND:

CONTAINMENT: Avoid runoff into storm sewers and ditches which lead to waterways. Contain spilled liquids with dry sorbents.

CLEANUP: Clean up spill immediately. Absorb spill with inert material (such as dry sand or earth), then place in a chemical waste container. Wash area with soap and water. Pick up wash liquid with additional absorbent and place in a chemical waste container. FOR SPILLS IN WATER:

CONTAINMENT: This material forms an emulsion in water. Stop or reduce contamination of any water. Isolate contaminated water

**CLEANUP:** Remove contaminated water for treatment or disposal.

# SECTION 7: HANDLING AND STORAGE

## END USER MUST READ AND OBSERVE ALL PRE-CAUTIONS ON PRODUCT LABEL.

DO NOT USE OR STORE near flame, sparks or hot surfaces. Use only in well ventilated area. Keep con-

DO NOT weld, heat or drill container. Replace cap or bung. Emptied container still contains hazardous or explosive vapor or liquid.

Keep pesticide in original container. Do not store or transport near food or feed. Do not contaminate food or feed. Do not put concentrate into food or drink containers. Do not dilute concentrate in food or drink containers. Store in a cool, dry place, out of direct

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL **PROTECTION**

END USER MUST READ AND OBSERVE ALL PRE-CAUTIONS ON PRODUCT LABEL.

EYE PROTECTION: Do not get this material in your eyes. Eye contact can be avoided by wearing protective evewear

RESPIRATION/VENTILATION: This material may be a respiratory irritant and, unless ventilation is adequate, the use of approved respiratory protection is recommended.

Wear approved respiratory protection when working with this material unless ventilation is adequate to keep airborne concentrations below recommended exposure standards.

. Use this material only in well ventilated areas.

SKIN PROTECTION: Do not get on skin or clothing. Skin contact should be minimized by wearing protective clothing including coveralls worn over short-sleeved shirt and short pants, socks, chemicalresistant footwear and chemical-resistant gloves

## SECTION 9: PHYSICAL AND CHEMICAL PROPER-TIES

APPEARANCE: Pale yellowish, clear liquid

ODOR: Mild aromatic odor MELTING POINT: NA **BOILING POINT: NDA** 

SPECIFIC GRAVITY: 0.92 @ 20/20°C SOLUBILITY: Emulsifiable in water

VAPOR PRESSURE: NA

**DISSOCIATION CONSTANT: NA** 

OCTANOL/WATER PARTITION COEFFICIENT: NA

pH: 5.7 (10% v/v) VISCOSITY: 18.5 cps

**CORROSION CHARACTERISTICS: Not corrosive** 

## SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable INCOMPATIBILITY: NDA IMPACT EXPLODABILITY: Not explosive OXIDATION/REDUCTION PROPERTIES: Not an oxidizing or reducing agent.

## SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE (Product Specific Information):

Eye Irritation: This product produced eye irritation in rabbits that cleared within 7 days after treatment. (Toxicity Category III)

Skin Irritation: This product produced moderate skin irritation in animals. (Toxicity Category III)

Dermal Toxicity: The dermal LD50 in rabbits is greater than 2 g/kg. (Toxicity Category III)

Oral Toxicity: The oral LD<sub>50</sub> in rats is 4733 mg/kg for males and 3773 mg/kg for females. (Toxicity Category

Inhalation Toxicity: The 4-hour LC<sub>50</sub> in rats is greater than 3.1 mg/l. (Toxicity Category IV)

Skin Sensitization: This product did not produce a

positive skin sensitization reaction in a Buehler Skin Sensitization Test.

# TOXICITY OF PYRIPROXYFEN TECHNICAL:

SUBCHRONIC: Subchronic oral toxicity studies conducted with Pyriproxyfen Technical in the rat, mouse and dog indicate a low level of toxicity. Effects observed at high dose levels consisted primarily of decreased body weight; increased liver weights; histopathological changes in the liver and kidney; decreased red blood cell counts, hemoglobin and hematocrit; altered blood chemistry parameters; and, at 5000 and 10000 ppm in mice, a decrease in survival rates. The NOELs from these studies were 1000 ppm (149.4 mg/kg/day) in mice, 100 mg/kg/day in dogs and 400

ppm (23.5 mg/kg/day) in rats. In a 4 week inhalation study of Pyriproxyfen Technical in rats, decreased body weight and increased water consumption was observed at 1000 mg/m³. The NOEL in this study was 482 mg/m³.

A 21-day dermal toxicity study in rats with Pyriproxyfen Technical did not produce any signs of dermal or

systemic toxicity at 1000 mg/kg/day.

CHRONIC/CARCINOGENICITY: Pyriproxyfen Technical has been tested in chronic studies with dogs. rats and mice. Dogs exposed to dose levels of 300 mg/kg/day or higher for 52 weeks showed overt clinical signs of toxicity, elevated levels of blood enzymes and liver damage. The NOEL in this study was 100 mg/kg/day. In a 78 week study in mice, dietary levels of 3000 ppm or greater produced gross and histopathological changes in the kidney. The NOEL in this study was 600 ppm. In a 2-year study in rats, dietary levels of 3000 ppm or greater produced decreased body weights in female rats. The NOEL in the rat study was 600 ppm. No oncogenic response was produced in mice or rats.

TERATOLOGY/DEVELOPMENTAL TOXICITY: Tests for developmental toxicity in rats and rabbits were conducted with Pyriproxyfen Technical. In the study conducted with rats, maternal toxicity (mortality, de creased body weight gain and food consumption and clinical signs of toxicity) was observed at doses of 300 mg/kg/day and greater. The maternal NOEL was 100 mg/kg/day. A transient increase in skeletal variations was observed in rat fetuses exposed to 300 mg/kg/day and greater. The NOEL for prenatal developmental toxicity was 100 mg/kg/day. An increased incidence of visceral and skeletal variations was observed postnatally at 1000 mg/kg/day. The NOEL for postnatal developmental toxicity was 300 mg/kg/day. In the study conducted with rabbits, maternal toxicity (clinical signs of toxicity including one death, decreased body weight gain and food consumption, and abortions or premature deliveries) was observed at oral doses of 300 mg/kg/day or higher. The maternal NOEL was 100 mg/kg/day. No developmental effects were observed in the rabbit fetuses. The NOEL for developmental toxicity in rabbits was 1000 mg/kg/day.

REPRODUCTION: A dietary rat reproduction study was conducted with Pyriproxyfen Technical. Systemic toxicity (reduced body weights, histopathological changes in the liver and kidney, and increased liver weight) was produced at 5000 ppm. The systemic NOEL was 1000 ppm. No effects on reproduction were produced even at 5000 ppm, the highest dose tested. MUTAGENICITY: Pyriproxyfen Technical was negative in the following tests for mutagenicity: Ames Assay with and without S9, unscheduled DNA synthesis in HeLa S3 cells, in vitro gene mutation in V79 Chinese hamster cells, and in vitro chromosomal aberration in Chinese hamster ovary cells.

#### TOXICITY OF OTHER INGREDIENTS:

This product contains a solvent mixture. Solvents, when inhaled, can cause nasal and respiratory irritation and central nervous system effects including dizziness, weakness, fatigue, nausea, headache and possibly unconsciousness and even death. Ingestion of solvents can cause gastrointestinal irritation, nausea, vomiting and diarrhea. Prolonged or repeated dermal exposures may cause drying, scaling and even blistering of

Reports have associated repeated and prolonged occupational overexposure to solvents with permanent brain and nervous system damage. Symptoms include fatigue, concentration difficulties, anxiety, depression, rapid mood swings and short-term memory loss. The reports are not clear with regard to the types of solvents that may cause these symptoms, and there is controversy among scientists to whether the condition exists or is caused by this type of product. Since many other diseases cause some or all of these conditions, a doctor should be consulted if any appear.

This product contains naphthalene which has been listed by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group

For a summary of the potential for adverse health effects from exposure to this product, refer to Section 3. For information regarding regulations pertaining to this product, refer to Section 15

# SECTION 12: ECOLOGICAL INFORMATION

AVIAN TOXICITY: Pyriproxyfen Technical is practically non-toxic to avian species. Test results include: Oral LD<sub>50</sub> mallard duck: greater than 2000 mg/kg Oral LD50 bobwhite quail: greater than 2000 mg/kg Dietary LC50 mallard duck: greater than 5200 ppm Dietary LC50 bobwhite quail: greater than 5200 ppm Reproduction bobwhite quail: NOEC = 600 ppm Reproduction mallard duck: NOEC = 600 ppm AQUATIC ORGANISM TOXICITY: Pyriproxyfen Technical is moderately to highly toxic to fish and moderately to very highly toxic to aquatic invertebrate species. Test results include:

Freshwater species:

LC50 (96 hr) Bluegill Sunfish: greater than 270 ug/l LC<sub>50</sub> (96 hr) Rainbow Trout: greater than 325 ug/l

LC<sub>50</sub> (21 day) Rainbow Trout: 90 ug/l

LC<sub>50</sub> (96 hr) Carp: 450 ug/l LC50 (96 hr) Killifish: 2660 ug/l

EC<sub>50</sub> (48 hr) Daphnia magna: 400 ug/l

MATC (21 day) Daphnia magna: 20 ppt

MATC (Early Life Cycle) Rainbow Trout: 5.4 ug/l

Estuarine species: LC<sub>50</sub> (96 hr) Sheepshead Minnow: greater than 1.02

ppm LC<sub>50</sub> (96 hr) Mysid Shrimp: 65 ppb

EC<sub>50</sub> (96 hr) Oyster Shell Deposition: 92 ppb

OTHER NON-TARGET ORGANISM TOXICITY: Pyriproxyfen Technical is practically non-toxic to bees. The acute contact LC50 in bees was greater than 100

## SECTION 13: DISPOSAL CONSIDERATIONS

END USERS MUST DISPOSE OF ANY UNUSED PRODUCT AS PER THE LABEL RECOMMENDA-TIONS.

**DISPOSAL METHODS:** Check governmental regulations and local authorities for approved disposal of this material. Dispose in accordance with applicable laws and regulations.

# SECTION 14: TRANSPORT INFORMATION

D.O.T. SHIPPING NAME: Insecticide, liquid, nonregulated

TECHNICAL SHIPPING NAME: Pyriproxyfen 12.2% Solution

RQ: 259 gallons

DOT HAZARD CLASS: Not applicable U.N./N.A. NUMBER: Not applicable

REMARKS: Regulated when shipped in bulk (>119

**EXCEPTION REQUIREMENT: 49 CFR 173.150** 

## SECTION 15: REGULATORY INFORMATION

REGULATIONS UNDER FIFRA: All pesticides are governed under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act). Therefore, the regulations presented below are pertinent only when handled outside of the normal use and applications of pesticides. This includes waste streams resulting from manufacturing/formulation facilities, spills or misuse of prod-ucts, and storage of large quantities of products containing hazardous or extremely hazardous substances. OTHER U.S. FEDERAL REGULATIONS:

OSHA: See Section 2.

CERCLA RQ\*: Product RQ = 259 gallons, Naphtha-

lene RQ =100 lb RCRA\*\*: Waste code for naphthalene is U165.

SARA TITLE III:

Sara (313) Chemicals: contains Naphthalene and Trimethylbenzene

Sara (311,312):

Immediate Health Effects: YES Chronic Health Effects: YES

Fire Hazard: YES

Sudden Release of Pressure: NO

Reactivity Hazard: NO Sara Section 302: NA

A component of this product is classified as an oil under Section 311 of the Clean Water Act (40 CFR 110) and the Oil Pollution Act of 1990. Discharge or spills which produce a visible sheen on either surface water, or in waterways / sewers which lead to surface water, must be reported to the National Response Center at 1-800-424-8802.

This product contains naphthalene which has been listed by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group

STATE REGULATIONS: Each state may promulgate standards more stringent than the federal government. This section cannot encompass an inclusive list of all state regulations. Therefore, the user should consult

state or local authorities.

PROPOSITION 65: WARNING: This product contains naphthalene which is known to the State of California to cause cancer.

\* RQ: Reportable Quantity

\*\* RCRA waste codes must be determined on a caseby-case basis (i.e., spill, processing waste, etc.). For information regarding potential adverse health effects from exposure to this product, refer to Sections 3 and 11.

## **SECTION 16: OTHER INFORMATION**

REASON FOR ISSUE: Revised Sections 3, 11 and 15 to reflect naphthalene being listed as a Group 2B carcinogen by IARC and added a California Proposition 65 warning

**REVISION NUMBER: 9 REVISION DATE: 02/21/2003** SUPERSEDES DATE: 10/30/2001 MSDS NUMBER: 0136

THE INFORMATION IN THIS MSDS IS BASED ON DATA AVAILABLE TO US AS OF THE REVISION DATE GIVEN HEREIN, AND BELIEVED TO BE CORRECT. CONTACT VALENT USA CORPORATION TO CONFIRM IF YOU HAVE THE MOST CURRENT MSDS

JUDGEMENTS AS TO THE SUITABILITY OF INFOR-MATION HEREIN FOR THE INDIVIDUAL'S OWN USE OR PURPOSES ARE NECESSARILY THE INDIVID-UAL'S OWN RESPONSIBILITY. ALTHOUGH REA-SONABLE CARE HAS BEEN TAKEN IN THE PREPA-RATION OF SUCH INFORMATION, VALENT EX-TENDS NO WARRANTIES, MAKES NO REPRESEN-TATIONS, AND ASSUMES NO RESPONSIBILITY AS TO THE ACCURACY OR SUITABILITY OF SUCH IN-FORMATION FOR APPLICATION TO THE INDIVID-UAL'S PURPOSES OR THE CONSEQUENCES OF ITS USE

**EMERGENCY TELEPHONE #: 1-800-892-0099** 

NDA - No Data Available NA - Not Applicable MSDS Number: 0136 Revision Number: 9 Revision Date: 02/21/2003